

**DECLARATION OF CONFORMITY – CLINICAL CHEMISTRY
according to Art. 5 (5) EU Regulation on *in vitro* diagnostic medical devices (EU) 2017/746
(IVDR) for in-house production of IVD in health institutions.**

We declare under our sole responsibility that the products listed below and manufactured by in-house production complies with all requirements of the IVD Regulation (EU) 2017/746, Annex I “General Safety and Performance Requirements”, which apply to it. The products was manufactured by us in our own premises on a non-industrial scale and is operated solely in our healthcare institution.

Product code

Information on the in-house devices (also known as laboratory developed tests, LDTs) used (see next page)

Medical Laboratories - Health institution

ARCHIMEDlife GmbH, International Medical Laboratories
located in Leberstrasse 20/2, 1110 Vienna, Austria

Device classification according to Annex VIII:

Class B and C (see next page)

CEO, Laboratory Director:

Dipl.-Ing. DDr. David C. Kasper

Head of Quality Management:

Andrea Konstantin

Place and date of issue:

Vienna, 13.10.2025

ARCHIMEDlife, a specialty medical laboratory based in Vienna, Austria, provides a wide range of diagnostic services to physicians, healthcare institutions, and private patients. With a strong commitment to medical excellence, ARCHIMEDlife conducts laboratory analyses in areas such as clinical chemistry, immunology, and molecular diagnostics with special focus on rare diseases (www.archimedlife.com).

The laboratory is accredited according to **EN ISO 15189:2022** (with accreditation no. #0407 from the Austrian government – Akkreditierung Austria), ensuring the highest standards of quality, competence, and reliability in medical laboratory services (please see: <https://akkreditierung-austria.gv.at/overview/14451549>)

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Product code, product number	Intended purpose	Risk class	Generic device group (EMDN)
SOP-M04	Quantitative determination of Lyso-GL-3/Lyso-Gb-3 by LCMS-MS from dried blood spots	C	W09010299
SOP-M08	Quantitative determination of lysosomal enzyme activities, LEA1, by LCMS/MS in dried blood spots	B	W01010199
SOP-M09	Quantitative determination of lysosomal enzyme activities, LEA2, by LCMS/MS in dried blood spots	B	W01010199
SOP-M10	Quantitative determination of Lyso-GL-1/Lyso-Gb1 by LCMS/MS from dried blood card	C	W09010299
SOP-M12	Quantitative determination of C26:0-lyso-LPC, adenosine, and deoxyadenosine by LC-MS/MS from dried blood spot card	B	W09010299
SOP-M18	Quantitative determination of acid lipase activity by LC-MS/MS from dried blood spot cards	B	W01010199
SOP-M19	Quantitative determination of palmitoyl protein thioesterase by LC-MS/MS from dried blood spot cards	B	W01010199
SOP-M20	Quantitative determination of lyso-sphingomyelin (lyso-SPM) by LC-MS/MS from dried blood spot card	C	W09010299
SOP-M22	Quantitative determination of lysosomal enzyme activity alpha-mannosidase by LC-MS/MS from dried blood spot cards	B	W01010199
SOP-M24	Quantitative determination of tetrol and t-CDCA by LC-MS/MS from dried blood spot cards	B	W09010299
SOP-M26	Quantitative determination of C16-sulfatides for the diagnosis of metachromatic leukodystrophy (MLD) by LC-MS/MS from dried blood spot card	B	W09010299
SOP-M31*	Quantitative determination of oxalate in urine by tandem mass spectrometry	C	W01010223
SOP-M32*	Hexose tetrasaccharide determination in urine by liquid chromatography–tandem mass spectrometry (LC-MS/MS)	C	W09010299
SOP-M33*	Quantitative determination of oxalate in plasma by tandem mass spectrometry	C	W01010223
SOP-M35*	Quantitative determination of creatinine in urine by tandem mass spectrometry	C	W01010207
SOP-M36*	Quantitative determination of GlcNAc(Man) ₂ by LC-MS from serum	C	W09010299
SOP-M37*	Quantitative determination of lyso-GL-1/lyso-Gb1 by LC-MS/MS from serum or plasma	C	W09010299
SOP-M38*	Quantitative LC-MS analysis of lyso-Gb3 and lyso-SM from serum	C	W09010299
SOP-I13*	Quantitative determination of oxalate in urine by tandem mass spectrometry	C	W01010223
SOP-I17	Quantitative determination of enzyme activities of hexosaminidases from dried blood spot card	B	W01010199

*fully validated; submitted for accreditation.